

## *USAF Dental Evaluation & Consultation Service*

### Gauze Report

20 Nov 2013

DECS was tasked on 4 November 2013 by AFMOA (Col Wagner) to provide a recommendation on the quality of a brand of gauze that two separate Air Force dental clinics raised concern with, and whether this brand/type of gauze posed a potential patient safety risk. The gauze in question is 2 in x 2 in, 12-ply Gauze Sponges (PRM21212C) by Caring International, Mundelein, IL (Medline). The product is made in China. After researching the standards for gauze sponges it was discovered that the American National Standards Institute (ANSI) and International Standards Organization (ISO) do not cover standards for gauze. Instead, quality and safety standards for this type of product fall under the United States Pharmacopia (USP) and the National Formulary (NF) which are designated under the Federal Food, Drug, and Cosmetic Act (FFDCA). The law recognizes USP and NF standards as guidelines for determining the identity, strength, quality and purity of certain products, gauze being one of them.



**Caring (Medline) non-USPVII gauze on the left, leaves pieces of material behind when the gauze is manipulated. Curity (Covidien) USP-VII gauze sponge on the right, leaves no residual material, after manipulation.**

These standards also establish specifications for labeling and packaging. It is important to note that if the intent is to use the gauze on or in a wound the gauze should meet standards set by USP. This would be indicated on the label of the gauze as USP Type VII Gauze, ensuring a premium product. Surgical and medical dressings and related products must generally meet the requirements of the USP for a number of specific characteristics, namely: material content, absorbency, fiber length and width, weight, thread count, solubility, adhesive strength, tensile strength, ignited residue, acidity or alkalinity, fatty matter, alcohol soluble dyes, sterility, labeling, packaging and storage. For many clinics the default gauze has been Curity from Kendall (Covidien). This product meets USP VII criteria. In addition to the USP standards, Covidien products have contracts through the Medical Material Enterprise Standardization Office (established within TRICARE) and are 100% US made. The cotton is grown in the United States and the open-end (rotor) spinning method of converting the cotton to yarn eliminates debris and short fibers to prevent entanglements and creates yarns with bundled individual fibers. This results in a product with loftier fibers, heavier dry weight and a greater absorbency capacity. Imported cotton utilizes a ring spinning technique which potentially has more debris and less absorbency and does not always meet the USP VII standards.

After speaking with representatives at Caring (Medline) there are many factors to consider in selecting a type of gauze for use in patient care. Manufacturers make several types of gauze. Some are low-end and are not to be considered for use on or in wounds. These low-end gauzes are used in other applications, such as wiping intact skin with alcohol prior to injection. It was this type of low-end gauze (Caring/Medline 2 in X 2 in, 12-Ply, PRM21212C, NOT USP VII) that was involved in the complaints. Caring makes a sterile 8-Ply gauze that has the USP VII label (NON25212). This type of gauze is the type that should be used in patient care. One base reported that the gauze they prefer (Curity/Covidien 2 in X 2 in, 12-Ply, USP VII), is no longer in the DMMLS system.

Our recommendation is that clinics wishing to use gauze sponges in the mouth for patient care, need to ensure that only USP VII labeled gauze is ordered. If contracting has selected another vendor then only USP VII gauze should be ordered.

On another note, we have been told that all contracting agencies use the Federal Acquisition Regulation in their contracts (Clause 52.225.5), meaning they must order from a country on the list, unless there is a specific waiver. China is not on the list. Waivers are supposedly very difficult to obtain. We are still waiting for a response from AFMOA/SGALE (Ft. Detrick) to find out why gauze from China is being ordered.

DECS recommends that only USP VII labeled gauze is used for intraoral applications in all USAF dental clinics.